

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Frederick L. Hall et al. Art Unit : 1647
Patent No. : 7,459,541 Examiner : Regina M. Deberry
Issue Date : December 2, 2008 Conf. No. : 4628
Serial No. : 10/733,852
Filed : December 10, 2003
Title : MATRIX-TARGETED FUSION POLYPEPTIDES FOR TISSUE
REGENERATION AND WOUND HEALING

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(d)

Applicants hereby petition for reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent application. The Issue Notification mailed November 12, 2008 for the above-referenced application indicates that the Patent Term Adjustment at issuance is 612 days. Reconsideration of the Patent Term Adjustment calculation to increase PTO Delay from 723 days to 1,023 days, and to increase Total PTA from 612 to 907 days, is respectfully requested.

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REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

A review of the Patent Term Adjustment History in the PAIR system shows that the United States Patent and Trademark Office (PTO) calculated the Patent Term Adjustment (PTA) as follows:

- 1) The PTO mailed a Notice To File Missing Parts on May 20, 2004. Applicants mailed a Response to the Notice To File Missing Parts on October 20, 2004 (received at the PTO on October 25, 2004). Applicants were accorded a delay of 61 days; however, the correct amount of delay (from August 20, 2004 to October 25, 2004) is 66 days, not 61 days. Applicants respectfully submit that the PTO's calculation of this Applicant Delay contains an error and that the correct Applicant Delay is 66 days.
- 2) The PTO mailed a delayed 14-month first non-final Office Action on December 7, 2005, thereby according a PTO Delay of 300 days. Applicants do not dispute herein this patent term adjustment calculation for this PTO "A Delay."
- 3) Applicants filed a Response to the December 7, 2005 non-final Office Action via Express Mail on April 7, 2006 (received at the PTO on April 7, 2006). Applicants were accorded a delay of 31 days. Applicants do not dispute herein this patent term adjustment for Applicant Delay.
- 4) Applicants filed a Response to the June 22, 2006 Final Office Action via EFS-Web on October 11, 2006 (received at the PTO on October 11, 2006). Applicants were accorded a delay of 19 days. Applicants do not dispute herein this patent term adjustment for Applicant Delay.
- 5) The application was filed on December 10, 2003 and the patent issued on December 2, 2008, more than three years later. Only 423 days of PTO delay was calculated for issuance of the patent after three years from filing. Applicants respectfully submit that the PTO's calculation of this PTO "B Delay" contains an error and that the correct PTO Delay for issuance beyond three years from filing is 723 days, as outlined further below.

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REMARKS

Applicants have calculated the PTA in accordance with the clear intent of Congress.

As outlined in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), the only way that periods of time can “overlap” is if they occur on the same day, and if an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. “A Delays” are defined as delays by the Office under 35 U.S.C. 154(b)(1)(A), which guarantees prompt PTO response. “B Delays” are defined as delays by the Office under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than 3-year application pendency.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, relies on the premise that the application was delayed under § 154(b)(1)(B) before the initial three-year period expired.

The *Wyeth* court determined that this construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years,” and that “B delay” begins once the PTO has failed to issue a patent within three years, not before.

In the current PTA calculation, the Office has only given credit for the larger of “A Delay” or “B Delay,” rather than the combined sum of “A Delay” and “B Delay” (which does not include any days after three years from filing where “A” and “B” delays overlap).

In this patent, “A Delay” should be calculated as 300 days, and “B Delay” should be calculated as 723 days. Thus, the total PTO Delay should be calculated as 1,023 days.

In consideration of the events described above, Applicants believe the PTA calculation of 612 days is incorrect. As such, Applicants respectfully request reconsideration of the patent term adjustment in the following manner:

- 1) Total PTO Delay should be calculated as 1,023 days;
- 2) Total Applicant Delay should be calculated as 116 days; and
- 3) Total PTA should be calculated as 907 days.

Applicants note that this patent is not subject to a terminal disclaimer.

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Please apply the fee of \$200 required under 37 C.F.R. § 1.18(e) and any other required charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

January 29, 2009
Date: _____



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